

## § 1304.50

chapter with a modification of its registration authorizing it to deliver, distribute, or dispense controlled substances by means of the Internet.

(6) The name, address, telephone number, professional degree, and States of licensure with State license number of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof.

(7) The following statement: “This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54)).”

[74 FR 15623, Apr. 6, 2009]

## **§ 1304.50 Disclosure requirements for Web sites of nonpharmacy practitioners that dispense controlled substances by means of the Internet.**

For a Web site to identify itself as being exempt from the definition of an online pharmacy by virtue of section 102(52)(B)(ii) of the Act (21 U.S.C. 802(52)(B)(ii)) and § 1300.04(h)(2) of this chapter, the Web site shall post in a visible and clear manner on its homepage, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, a list of the DEA-registered nonpharmacy practitioners who are affiliated with the Web site. Any nonpharmacy practitioner affiliated with such a Web site is responsible for compliance with this section. An institutional practi-

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tioner that otherwise complies with the requirements of the Act and this chapter will be deemed to meet the requirements of this section if, in lieu of posting the names of each affiliated individual practitioner, it posts its name (as it appears on its Certificate of Registration) in a visible and clear manner on its homepage and in a manner that identifies itself as being responsible for the operation of the Web site.

[74 FR 15623, Apr. 6, 2009]

## **§ 1304.55 Reports by online pharmacies.**

(a) Each online pharmacy shall report to the Administrator the total quantity of each controlled substance that the pharmacy has dispensed each calendar month. The report must include the total quantity of such dispensing by any means, regardless of whether the controlled substances are dispensed by means of the Internet. Thus, such reporting shall include all controlled substances dispensed via Internet transactions, mail-order transactions, face-to-face transactions, or any other means. However, the pharmacy is not required to describe in its report to the Administrator such means of dispensing. Such reporting is required for every calendar month in which the total quantity of controlled substances dispensed by the pharmacy meets or exceeds one of the following thresholds:

(1) 100 or more prescriptions for controlled substances filled; or

(2) 5,000 or more dosage units dispensed of all controlled substances combined.

(b) Each online pharmacy shall report a negative response if, during a given calendar month, its total dispensing of controlled substances falls below both of the thresholds in paragraph (a) of this section.

(c) The reporting requirements of this section apply to every pharmacy that, at any time during a calendar month, holds a modified registration authorizing it to operate as an online pharmacy, regardless of whether the online pharmacy dispenses any controlled substances by means of the Internet during the month.

(d) Reports will be submitted to DEA electronically via online reporting,

electronic file upload, or other means as approved by DEA.

(e) Reports shall be filed every month not later than the fifteenth day of the month succeeding the month for which they are submitted.

(f) An online pharmacy filing a report under paragraph (a) of this section shall utilize the National Drug Code number assigned to the product under the National Drug Code System of the Food and Drug Administration, and indicate the total number of dosage units dispensed for each such National Drug Code number.

(g) Records required to be kept under this section must be kept by the registrant for at least two years from the date of such records. The information shall be readily retrievable from the ordinary business records of the registrant and available for inspection and copying by authorized employees of the Administration.

[74 FR 15623, Apr. 6, 2009]

## **PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES**

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AUTHORITY: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

SOURCE: 70 FR 16911, Apr. 1, 2005, unless otherwise noted.

## **Subpart A—General Requirements**

### **§ 1305.01 Scope of part 1305.**

Procedures governing the issuance, use, and preservation of orders for Schedule I and II controlled substances are set forth generally by section 308 of the Act (21 U.S.C. 828) and specifically by the sections of this part.

### **§ 1305.02 Definitions.**

Any term contained in this part shall have the definition set forth in the Act or part 1300 of this chapter.

### **§ 1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.**

Either a DEA Form 222 or its electronic equivalent as set forth in subpart C of this part and Part 1311 of this chapter is required for each distribution of a Schedule I or II controlled substance except for the following:

(a) Distributions to persons exempted from registration under Part 1301 of this chapter.

(b) Exports from the United States that conform with the requirements of the Act.

(c) Deliveries to a registered analytical laboratory or its agent approved by DEA.

(d) Delivery from a central fill pharmacy, as defined in §1300.01(b)(44) of this chapter, to a retail pharmacy.